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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/532,704

05/02/2006

Michael E. McClurken

TLK025

2680

32047

7590

10/20/2010

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EXAMINER

HUPCZEY, JR, RONALD JAMES

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

10/20/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/532,704	Applicant(s) MCCLURKEN ET AL.	
	Examiner RONALD HUPCZEY, JR	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-21, 23-32 and 39-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-21, 23-32 and 39-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 April 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendments and remarks, filed August 30th, 2010, have been fully considered by the Examiner. Currently, claims 19-21, 23-32 and 39-43 are pending with claims 1-18, 22 and 33-38 cancelled, claims 19-21 and 23-31 amended and claims 39-43 newly added. The following is a complete response to the August 30th, 2010 communication.

Claim Rejections - 35 USC § 103

2. Claims 19-21, 23-29 and 31-32 and 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pennybacker et al (US Pat. No. 5,637,110) in view of Levin (US Pat. No. 5,827,281).

Regarding claims 19 and 39-43, Pennybacker discloses a fluid-assisted electrosurgical (see col. 6; 50-64) device to treat tissue comprising (see figures 1 and 26) an end effector comprising a first member and a second member (jaw unit **12** with jaws **170**), the first member and the second member pivotally connected (connected via pivot pin **192**), at least one of the first member and the second member electrically coupled (see col. 6; 50-64) to an electrical connector (terminal pin **94**) connectable to a radio frequency power source (current source **95**), a fluid passage (passage formed by flat **146** on rod **50** and tube **51**) in fluid communication with at least one fluid outlet (fluid exit at the end of flat **146**) positioned to expel a fluid to the end effector and obstructed from contact with tissue by at least one of the members. While Pennybacker shows in the embodiments of figures 1 and 26 that the end effector with the first and second member is an electrosurgical grasper having conventional jaws, Pennybacker further discloses that the convention jaws can be replaced with scissor jaws capable of scissor-like cutting (see col. 9; 48-54). Pennybacker fails to show the structure or shape of these scissor jaws.

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Levin discloses a similar electrosurgical device (as best seen in figures 4-7) as that of Pennybacker including an end effector having a first and second blade member (jaws **22A**, **22B**) pivotally connected and arranged to cut tissue (see col. 2; 53-56). Levin further discloses that the first and second blade members comprise respective first and second blade shearing edges extending to a distal end of the respective first and second blade member (see figures 4 and 6 displaying the edge defined on each jaw member **22A**, **22B**). Levin additionally shows that each blade member has a bulbous portion protruding from the blade member, the bulbous portion being on an exterior side of the blade member proximally adjacent the distal end (taken as the end of the each jaw **22A**, **22B** where it meets the tips **30A**, **30B**) of the blade member (see figures 4-6 displaying the rounded, spherically-shaped top/exterior portion of each of the jaws **22A**, **22B**). Levine discloses (see figures 4-7) that the bulbous portion has a generally spherical shape (rounded portions of the jaws **22A**, **22B** being of or related to a portion of a sphere), that the spherical bulbous portions have an electrically conductive spherical surface (electrically conductive surface of each bulbous portion of the jaws **22A**, **22B** which are covered by the insulation layer **27**), that each bulbous portion is on an exterior surface of the blade member which opposes an interior side of the bladed member having a shearing surface (at least a portion of the rounded portions of the jaws **22A**, **22B** are opposed in the interior surfaces contained on the jaws) and that the bulbous portion protrudes from a convex side of the blade member (for example, with the far right side of the upper blade member in figure 4 taken as a convex side, the upper rounded, bulbous portion would protrude from the end of that side at the top portion of it). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the electrosurgical scissor arrangement as shown by Levin as the

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electrosurgical scissors of Pennybacker to provide for a combined device which can both sever and coagulate tissue at a target tissue site. The combined functionality eliminates the need for two separate tools to be used during treatment thereby reducing treatment time and the chance of complications arising due to multiple insertions of different devices.

Regarding claim 20, Pennybacker discloses that the end effector is supplied with monopolar electrosurgical energy thereby making the combined electrosurgical scissors as in above claim 19 monopolar (see col. 6; 50-64).

Regarding claim 21, Pennybacker discloses that the device functions electrosurgically and in a laparoscopic manner (see abstract, figure 1 and col. 6; 50-64).

Regarding claim 23, Pennybacker fails to disclose any specifics of the blade structure. Levin discloses (see figures 4-7) that the first blade member comprises a first blade member exterior surface, the second blade member comprises a second blade member exterior surface and at least one of the first blade member exterior surface and the second blade member exterior surface at least partially comprises an electrically insulative material (insulative layer **27**). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the end effector/blade arrangement of Levin as the scissor arrangement of Pennybacker to provide for a combined electrosurgical device which only supplies electrosurgical energy to a targeted portion of tissue. By supplying an insulative layer as in Levin, non-target tissue is shielded from the effects of the applied electrosurgical energy thereby preventing unwanted collateral damage.

Regarding claim 24, Pennybacker fails to disclose any specifics of the blade structure. Levine discloses (see figures 4-7) that the first blade member comprises a first blade member

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shearing surface (interior surface of **22A**), the second blade member comprises a second blade member shearing surface (interior surface of **22B**) and the first blade member shearing surface and the second blade member shearing surface face one another when the first blade member and the second blade member are in a closed position (see position in figure 6). Therefore, it would have been obvious to one of ordinary skill in the art that in utilizing the structure of Levin as the scissors of Pennybacker as in claim 19 above, that the end effector would contain such a structural arrangement.

Regarding claim 25, Pennybacker discloses (see figure 8 and col. 9; 5-18) an elongated shaft, a lumen located within the shaft; and the lumen providing a portion of the fluid passage (extension of tube **51** with space therein and the distal opening at the end of the tube **51**).

Regarding claim 26, Pennybacker discloses an elongated shaft and the at least one fluid outlet is located within the shaft (extension of tube **51** with space therein and the distal opening at the end of the tube **51**).

Regarding claim 27, Pennybacker discloses a push rod, a lumen located within the push rod and the lumen providing a portion of the fluid passage (extension of tube **51** with space therein and the distal opening at the end of the tube **51**).

Regarding claim 28, Pennybacker discloses that the fluid passage passes through a connector member that couples the blade members to a push rod (see figures 13 and 20 with arm **163** providing such a coupling).

Regarding claim 29, Pennybacker discloses that the at least one fluid outlet is provided by a connector member which couples the blade members and a push rod (see figures 13 and 20, the relation of **51**, **50**, and **63** and in view of col. 9; 5-18).

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Regarding claims 31 and 32, Pennybacker fails to disclose any specifics of the blade structure. Levine discloses (see figures 4-7) that the first blade member comprises a first blade member exterior surface (exterior surface of **22A**), the second blade member comprises a second blade member exterior surface (exterior surface of **22B**) wherein at least one of the exterior surfaces is configured to slide along tissue while the exterior surface is coupled adjacent the tissue with a fluid expelled from the fluid outlet and radio frequency power is provided to the tissue from the scissors and wherein at least one of the exterior surfaces is further configured such that the fluid expelled from the fluid outlet forms a localized fluid coupling between a surface of the tissue and the exterior surface when the exterior surface is located adjacent the surface of the tissue. Therefore, it would have been obvious to one of ordinary skill in the art that in utilizing the structure of Levin as the scissors of Pennybacker as in claim 19 above, that the end effector would contain such a structural arrangement. It is noted that the "configured to" language in the claim is being interpreted as a recitation of intended use and/or functional language and as such, it is the Examiner's position that the combined device of Pennybacker and Levin is capable of performing such a function. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

3. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pennybacker et al (US Pat. No. 5,637,110) in view of Levin (US Pat. No. 5,827,281) as applied to claim 19 above and further in view of Rydell (US Pat. No. 5,352,222).

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Regarding claim 30, Both Pennybacker and Levin fail to disclose that at least one of the blade members is curved. Rydell discloses a similar electrosurgical device as that of Pennybacker and Levin having an end effector with a first and second blade member (see figure 2). Rydell further discloses that the first and second blade member is curved (see shape in figure 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the curved shaped of the blade members of Rydell to the blade members of the combined device of Pennybacker and Levin. Rydell discloses the interchangeability between the two variations, straight and curved, in col. 4; 35-45 and one of ordinary skill would readily recognize that such a change is an obvious design choice given the prior art and the desire to access different target areas within a patient's body.

Response to Arguments

4. Applicant's arguments with respect to the rejections the claims have been considered but are moot in view of the new ground(s) of rejection. In light of Applicant's amendment to claim 19 specifying new subject matter not previous present in the claims (the first and second shearing edges, location of the at least one bulbous portion) has necessitated the Examiner to proffer the new interpretation of the Levine reference above. Previously, the Examiner characterized the tips (30A and 30B) of Levine as the bulbous portions. Due to the amendment to claim 19, the rounded top portion of jaw 22A and the round bottom portion of the jaw 22B as shown in figures 4 and 6 are being interpreted as the rounded "bulbous portions". New claims 39-43 have also been addressed in light of the new interpretation and given the broadest reasonable interpretation afforded to one of ordinary skill in the art in light of the specification. Applicant is invited to

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contact the Examiner if the above interpretation of the art is unclear or if Applicant would like further clarification.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD HUPCZEY, JR whose telephone number is (571)270-5534. The examiner can normally be reached on Monday - Friday, 9 A.M. to 5 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ronald J. Hupczey/
Examiner, Art Unit 3739

/Michael Peffley/
Primary Examiner, Art Unit 3739

RJH